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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,167	10/17/2001	Chunhua Yan	CL001303	3910

25748 7590 10/06/2004

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,167	YAN ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,8,9 and 24-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/6/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 4, 8-9, and 24-37 are pending in the application.
- [2] Applicants' amendment to the claims, filed August 06, 2004, is acknowledged.
This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicants' amendment to the specification, filed August 06, 2004, is acknowledged.
- [4] Receipt of an information disclosure statement, filed August 06, 2004, is acknowledged.
- [5] Applicants' arguments filed on August 06, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [6] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

- [7] In view of applicants' amendment to the specification, the objection to the specification for failing to properly identify the drawings as set forth in item [11] of the Office action mailed April 06, 2004 is withdrawn.

Claim Objections

[8] In view of the amendment to the claims, the objected to claim 25 as set forth at item [12] of the Office action mailed April 06, 2004, is withdrawn.

Claim Rejections - 35 USC § 101 and 112, First Paragraph

[9] The rejections of claims 4, 8-9, and 24-37 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph is maintained for the reasons of record as set forth at items [13] and [15] of the Office action mailed April 06, 2004 and for the reasons stated below.

[10] RESPONSE TO ARGUMENTS: Applicants continue to argue that the claimed polynucleotide is useful in the treatment and/or diagnosis of developmental disorders, allegedly established by the references of Brandenberger et al. and Morimura et al. Applicants assert that based on these references, the utility of nephronectins is well-established because "nephronectins have been characterized as playing important roles in specific aspects of development" and that a skilled artisan would recognize the use of the claimed polynucleotide in the treatment/diagnosis of developmental disorders. Applicants' argument is not found persuasive.

As stated in a previous Office action and undisputed by applicants, there is no indication in the specification and prior art that the claimed nucleic acids encode biologically active polypeptides, either by direct assay or by comparison of the known nephronectin sequences, showing residues that are shared with SEQ ID NO:2 that are required for nephronectin biological activity. In the absence of such evidence, a skilled artisan would recognize that further experimentation is required to determine whether SEQ ID NO:2 has nephronectin biological activity. Even assuming *arguendo* the

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asserted uses of the claimed polynucleotides do not require nephronectin biological activity, it is noted that the specification and the prior art fail to provide *specific* guidance for using the claimed polynucleotide for treating or diagnosing a *specific* developmental disorder. In the absence of such guidance, further experimentation is required for a skilled artisan to determine those specific diseases – if any – that can be treated and/or diagnosed and the methods by which such treatment/diagnosis is carried out using the claimed polynucleotide. Consequently, the asserted utilities for the claimed polynucleotide for treatment and/or diagnosis of developmental disorders are not specific and substantial.

Conclusion

[11] Status of the claims:

- Claims 4, 8-9, and 24-37 are pending.
- Claims 4, 8-9, and 24-37 are rejected.
- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571)

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272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman

Primary Examiner

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09-28-04